

EXECUTIVE OFFICE OF THE PRESIDENT  
THE UNITED STATES TRADE REPRESENTATIVE  
WASHINGTON, D.C. 20508

**MAY 29 2007**

The Honorable Henry Waxman  
Chairman  
Committee on Oversight & Government Reform  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your letter outlining your concerns regarding the intellectual property rights provisions of U.S. free trade agreements, and the relationship of those provisions to the public health objectives of our trading partners.

I apologize for the delay in this reply. As I know you are aware, a number of us in the Administration have been involved in active discussions with Congressional leaders on a variety of trade policy issues in recent months, including those raised in your letter. Having concluded a landmark bipartisan agreement with respect to several pending free trade agreements on May 10, I am able to respond more fully to the issues you raised.

The Administration's approach to these issues is rooted in our strong commitment to the 2001 Doha Declaration on the TRIPS Agreement and Public Health and to the subsequent TRIPS Agreement amendment making it possible for developing countries that lack pharmaceutical manufacturing capacity to import medicines needed to address health emergencies. Indeed, the United States was the first WTO Member to submit its formal acceptance of the amendment making this "TRIPS public health" solution a permanent part of the TRIPS Agreement.

Reflecting the guidance set out in the Trade Act of 2002, our free trade agreements seek to establish adequate and effective protection of intellectual property rights by U.S. trading partners, through provisions that reflect standards of protection that are similar to those found in U.S. law, while also respecting the Doha Declaration. We are confident that we have achieved these complementary objectives with respect to our FTAs.

Under the terms of the bipartisan agreement reached on May 10, we will be incorporating certain additional flexibilities in connection with the FTAs we have negotiated with Peru, Colombia, and Panama. Specifically, the agreement with the Congressional leadership entails the following elements related to intellectual property, medicines, and health:

- Clarification that the period of protection for test data for pharmaceuticals by developing country FTA partners will generally not extend beyond the period that such protection is available for the same product in the United States, coupled with a provision that will encourage our partners to process marketing approval applications for innovative drugs in a timely manner.
- Clarification that developing country FTA partners may implement exceptions to normal rules for protecting test data if necessary to protect public health.

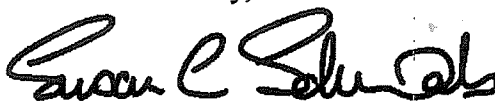
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- A more flexible approach, for developing country partners, to restoring patent terms to compensate for processing delays. This flexibility is accompanied by new provisions stipulating that trading partners will make best efforts to process patent and marketing approval applications expeditiously.
- More flexibility in terms of the types of procedures that developing country partners may implement to prevent the marketing of patent-infringing products.
- Integration within the intellectual property chapter of a recognition that nothing in the chapter affects the ability of our FTA partners to take necessary measures to protect public health by promoting access to medicines for all, and a statement affirming mutual commitment to the 2001 Doha Declaration on the TRIPS Agreement and Public Health.

These modifications are aimed at further ensuring that developing country free trade agreement partners are able to achieve an appropriate balance between fostering innovation in, and promoting access to, life-saving medicines.

Thank you again for your views on these important issues.

Sincerely,

A handwritten signature in black ink, appearing to read "Susan C. Schwab". The signature is fluid and cursive, with the first name "Susan" and last name "Schwab" being the most prominent parts.

Susan C. Schwab